



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPEAL BRIEF FOR THE APPELLANTS

Ex parte MAJEED et al

POTASSIUM HYDROXYCITRATE FOR THE SUPPRESSION OF APPETITE
AND INDUCTION OF WEIGHT LOSS

Serial Number: 09/083,122
Filed: May 22, 1998
Appeal Number: Unknown
Group Art Unit: 1623
Examiner: Oh, T.

A check in the amount of One Hundred and Fifty Dollars (\$150.00, for a small entity) is enclosed to cover the official fee for this Appeal Brief. In the event that any additional fees are required with respect to this paper, please charge Counsel's Deposit Account No. 01-2300.

Respectfully submitted,

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(1) Real Party in Interest

The real party in interest is Sabinsa Corporation.

(2) Related Appeals and Interferences

There are no related appeals or interferences known to appellants.

(3) Status of Claims

Claims allowed: None.

Claims objected to: None.

Claims rejected: 1, 2 and 5-17.

(4) Status of Amendments

An amendment was filed after final rejection on May 11, 2000 to cancel claims 7-15 in order to reduce the number of issues for appeal. As of May 24, 2000, Examiner Oh indicated that the amendment filed on May 11, 2000 had not been received. In the event that the Examiner receives that amendment of May 11, 2000 along with this Appeal Brief, appellants respectfully request that the amendment of May 11, 2000 be entered. However, the balance of this Appeal Brief assumes that the amendment of May 11, 2000 has not yet been entered.

(5) Summary of Invention

The invention is directed to a process of producing potassium hydroxy citric acid not in the form of a lactone and the potassium hydroxy citric acid made by said process. The process comprises extracting Garcinia fruit with an alcohol, treating the alcohol extract with KOH to obtain a treated extract, refluxing the treated extract to obtain potassium hydroxy citrate precipitate, isolating the precipitate, washing the precipitate with alcohol, and drying the precipitate to obtain potassium hydroxy citric acid.

(6) Issues

Whether claims 1, 2 and 5-17 are unpatentable under 35 U.S.C. 103 over Lewis (*Methods in Enzymology*, vol. XIII, pp. 615-616, 1969) in view of Lowenstein (US 3,764,692).

(7) Grouping of Claims

Claims 1, 2 and 5-17 should be separated into two groups.

Group I. Claims 1, 2, 5, 6, 16 and 17, drawn to a process of producing potassium hydroxy citric acid not in the form of a lactone.

Group II. Claims 7-15, drawn to a compound made by the process of Group I.

The claims of Groups I and II do not stand or fall together because the claims of Groups I and II are patentably distinct. The claims of Groups I and II are patentably distinct because the patentability of the process of Group I and the compound of Group II involve different factors. For instance, if a prior art reference were to anticipate or

render obvious the compound of Group II, i.e. claims 7-15, the reference would not necessarily anticipate or render obvious the process of Group I, i.e. claims 1, 2, 5, 6, 16 and 17 (e.g. the reference may not teach or suggest the steps of the claimed process of Group I).

(8) Argument

I. Claims 1, 2, 5, 6, 16 and 17 would not have been obvious over Lewis in view of Lowenstein.

The claimed process (claim 1 is representative) is compared with the teachings of Lewis in the following table.

<u>Claimed Process</u>	<u>Process of Lewis</u>
a) providing Garcinia fruit;	(1) providing fruit rind of <i>Garcinia cambogia</i> (p. 615, line 20);
b) extracting the fruit with alcohol to obtain an extract;	(2) autoclaving the fruit rind with water to obtain a water extract (p. 615, lines 20-21);
	(3) cooling and filtering the water extract to obtain a dark brown aqueous filtrate (p. 615, lines 21-24);
	(4) concentrating the dark brown aqueous filtrate (p. 615, line 24);

(5) treating the concentrated dark
brown aqueous filtrate with
ethanol and to convert a
pectinous material into a
precipitate (p. 615, lines 25-26);

(6) removing the precipitate by filtration
to obtain an acidic aqueous
filtrate (p. 615, lines 26-27);

c) repeating step b) to obtain another extract;

d) combining the extracts of steps b)
and c) to obtain a combined extract;

e) treating the combined extract with
KOH to obtain a treated extract;

(7) treating the acidic aqueous filtrate
with 40% KOH to obtain a
heavy oily liquid, which
apparently is the potassium
salt of hydroxy citric acid, mixed
with alcohol, water and KOH
(p. 615, lines 14, 15, 27, and
28; p. 616, line 1);

(8) letting the heavy oil liquid settle
and removing a supernatant
to obtain the heavy oily

- liquid (p. 616, lines 1-2);
- (9) washing the heavy oily liquid with
60% ethanol 5 times and
absolute ethanol 3 times and
letting it stand overnight
(p. 616, lines 2-6);
- f) refluxing the treated extract to obtain
potassium hydroxy citrate precipitate;
- (10) decanting ethanol to obtain a
yellow semisolid (p. 616,
lines 6-7); and thereafter
- g) isolating the precipitate;
- (11) drying the yellow semisolid in
vacuo to obtain a salt, which
is potassium hydroxy citric
acid (p. 615, line 16; and
p. 616, lines 7-8).
- h) washing the precipitate with an alkyl
alcohol to obtain a washed
precipitate; and thereafter
- i) drying the washed precipitate to obtain
dried potassium hydroxy citric acid.

The claimed process differs from the process of Lewis at least in the following ways.

- (i) The claimed process starts with the whole Garcinia fruit, while the process of Lewis starts with the rind of Garcinia fruit.
- (ii) The claimed process extracts the whole Garcinia fruit with alcohol. In contrast, the process of Lewis follows a laborious procedure of extracting the Garcinia fruit rind with water, filtering the water extract to obtain a filtrate, concentrating the filtrate, and treating the filtrate with ethanol to remove a contaminant, i.e. the pectinous material, to be discarded as a precipitate leaving behind the acidic aqueous filtrate.
- (iii) The claimed process treats the alcohol extract with KOH (see step e)), but the process of Lewis treats the aqueous filtrate with KOH (see step (7) in the table above).
- (iv) In the claimed process, after adding KOH, reflux is performed to obtain a precipitate of potassium hydroxy citric acid (see step f)), but, in the process of Lewis, after the addition of KOH, there is no refluxing (see step (7)) and step (7) obtains the heavy oily liquid which has to be washed with ethanol in step (9).
- (v) Steps a)-h) of the claimed process obtain a precipitate of potassium hydroxy citric acid of high purity requiring only one wash with alcohol. In contrast, steps (1)-(10) of the process of Lewis obtain a heavy oily liquid of potassium hydroxy citric acid of apparently low purity because Lewis requires washing the oily liquid 8 times to purify the potassium hydroxy citric acid as a yellow semisolid.
- (vi) The claimed process is relatively simple, while the process of Lewis is rather laborious. The claimed process involves extracting Garcinia fruit with alcohol twice, treating the alcohol extract with KOH and refluxing to obtain potassium hydroxy citric acid (see steps b)-g) in the table above). However, the process of Lewis requires

laborious procedures involving extracting Garcinia fruit rind with water, filtering and concentrating the water extract, adding ethanol to precipitate the pectinous material, removing the pectinous material precipitate by filtration, treating the filtrate with KOH, removing the supernatant to obtain the heavy oily liquid, washing the heavy oily liquid with ethanol 8 times, and discarding the ethanol to obtain potassium hydroxy citric acid as the yellow semisolid (see steps (2)-(10) in the table above).

Appellants note that Lowenstein fails to cure the deficiencies of Lewis because Lowenstein discloses that hydroxy citric acid can be isolated using the process of Lewis, so Lewis provides no reason of modifying the process of Lewis.

Regarding difference (i), there would have been no motivation to modify the process of Lewis by replacing the fruit rind with the whole Garcinia fruit as the starting material because Lewis already discloses that hydroxy citric acid is the major organic acid present in the fruit rind of Garcinia (p. 615, footnote 10).

Regarding difference (ii), the claimed process directly treats Garcinia fruit with alcohol, but the process of Lewis treats Garcinia fruit rind with water, filters the water extract to obtain a filtrate, concentrating the filtrate, and treating the concentrated filtrate with ethanol to precipitate a contaminant. The Advisory Action of March 10, 2000 states that there is little difference between the Garcinia fruit and Garcinia fruit rind for the purpose of producing hydroxycitric acid because the Garcinia fruit contains water and the Garcinia fruit rind contains little water (see page 2 of the Advisory Action). Appellants respectfully disagree. Appellants note that the purposes of the alcohol treatment in the claimed process and the process of Lewis are different. In the claimed

process, the alcohol is used to extract hydroxy citric acid from the Garcinia fruit in steps (b) and (c). In contrast, the purpose of adding alcohol to the water extract of Garcinia fruit rind in the process of Lewis is to cause a contaminant to precipitate to allow the removal of the contaminant (see steps (5) and (6) in the table above). Based on the teachings of Lewis, there would have been no reason to modify the process of Lewis by using the alcohol for a completely different purpose in order to treat the whole fruit of Garcinia directly with alcohol to extract hydroxy citric acid instead of extracting the fruit rind of Garcinia with water and treating the concentrated water extract with alcohol to precipitate out the contaminant. Since Lowenstein suggests using the process of Lewis to obtain hydroxy citric acid and Lowenstein offers no suggestion to modify the process of Lewis, difference (ii) is one of reasons why step b) of the claimed process would not have been obvious.

Additionally, regarding difference (ii), appellants note that the purpose of adding alcohol to extract hydroxy citric acid in step b) of the claimed process is unexpected based on the teaching of Lewis. Lewis teaches that the potassium salt of hydroxy citric acid is insoluble in alcohol because Lewis washes potassium salt of hydroxy citric acid with ethanol (p. 616, lines 2-6). Thus, there would have been no reasonable expectation that alcohol can also be used to extract hydroxy citric acid. This is another reason why steps b) and c) of the claimed process would not have been obvious.

Also, regarding difference (ii), the Advisory Action argues that page 616, lines 21-22, of Lewis teaches that water, alcohol and acetone can be used to extract Garcinia fruit. Appellants respectfully disagree because page 616, lines 21-22, of Lewis

concerns another process, i.e. Method B, which is different from the Method A in pages 615-616 relied upon by the Examiner in his obviousness rejection. Furthermore, page 616, lines 21-22, does not mention alcohol. This is another reason why, due to difference (2), steps b) and c) of the claimed process would not have been obvious over Lewis in view of Lowenstein.

Appellants submit that the Advisory Action's argument that water, acetone and alcohol all serve the same purpose regarding extraction of hydroxycitric acid is wrong. This is because, if water, acetone and alcohol were to serve the same purpose in extraction, why would Lewis teaches in page 616, lines 21-22, to start the extraction of the Garcinia fruit rind with acetone and then with water (why not using water alone)? Furthermore, water, acetone and alcohol are solvents having different degrees of polarity, so the substances extracted with water, acetone and alcohol need not be the same.

Regarding difference (iii), treating the alcohol extract with KOH in the claimed process is patentably distinct from treating the aqueous filtrate with KOH in the process of Lewis. The alcohol extract in the claimed process contains substances in the Garcinia fruit that are soluble in alcohol. In contrast, in the process of Lewis, the aqueous filtrate contains water soluble substances. Substances soluble in water may not be soluble in alcohol. For instance, potassium hydroxy citric acid is soluble in water but not soluble in alcohol. There would have been no motivation or reason of modifying the process of Lewis by using the alcohol extract of the Garcinia fruit instead of the aqueous filtrate made from the water extract of the Garcinia fruit rind.

Regarding difference (iv), the claimed process requires refluxing the alcohol extract treated with KOH to obtain a precipitate of potassium hydroxy citric acid, but, in the process of Lewis, after the addition of KOH to the aqueous filtrate, there is no refluxing and the heavy oily liquid is obtained. There would have been no motivation or suggestion to modify the process of Lewis by replacing the addition of KOH to the aqueous filtrate with no refluxing with the addition of KOH to the alcohol extract with refluxing. The Advisory Action argues that difference (iv) is obvious because the addition of 40% of KOH to the aqueous filtrate generates an excessive heat, which the Examiner asserted to be closely equivalent to refluxing. Appellants respectfully disagree because the amount of heat generated by the addition of 40% KOH to the aqueous filtrate would be much less than the amount of heat required to perform refluxing. Thus, the addition of 40% KOH is not equivalent to refluxing. The Advisory Action also argues that reversing the steps of the multi-step process of Lewis to arrive at step (e) in claim 1 would have been obvious because reversing the steps in a multi-step process of the prior art would have been obvious. Appellants respectfully disagree because there is a technical reason why certain steps are performed in a certain order in the multi-step process of Lewis. One of ordinary skill in the art would not have reasonably expected that simply reversing the steps of Lewis would work.

Regarding difference (v), the claimed process obtains potassium hydroxy citric acid as a precipitate of high purity requiring only one wash with alcohol. In contrast, the process of Lewis obtains a heavy oily liquid of potassium hydroxy citric acid of apparently low purity requiring washing for 8 times with ethanol to purify the potassium

hydroxy citric acid as a yellow semisolid. Difference (v) highlights the simplicity of the claimed process versus the process of Lewis. There would have been no suggestion in the prior art that modifications of the process of Lewis to arrive at the claimed process would obtain potassium hydroxy citric acid as a precipitate of high purity requiring only one wash with alcohol.

Regarding difference (vi), the claimed process is relatively simple, while the process of Lewis is rather laborious. There would have been no suggestion of modifying the process of Lewis to arrive at the claimed process because there would have been no reasonable expectation that the modification would be successful. The claimed process has the unexpected advantage of being simple and yet can yield potassium hydroxy citric acid of high purity. This is another reason why the claimed process would not have been obvious over Lewis in view of Lowenstein.

Due to differences (i)-(vi) discussed above between the claimed process and Lewis and due to the lack of teachings in Lowenstein to remedy these differences of Lewis, claims 1, 2, 5, 6, 16 and 17 should not have been obvious over Lewis in view of Lowenstein.

II. Claims 7-15 would not have been obvious over Lewis in view of Lowenstein.

If the amendment, for cancelling claims 7-15, filed on May 11, 2000 is entered after the filing of this Appeal Brief, the rejection of claims 7-15 would become moot. In the event that the amendment of May 11, 2000 has not been entered, appellants present the following arguments against the rejection.

Lewis teaches that the potassium hydroxy citric acid (the yellow semisolid) is very hygroscopic, but the potassium hydroxy citric acid prepared by the claimed process is not hygroscopic (see claim 10). This shows that the potassium hydroxy citric acid of claims 7-15 is different from the potassium hydroxy citric acid produced by the process of Lewis. Therefore, claims 7-15 would not have been obvious over the references cited.

With the above reasoning, reversal of the obviousness rejection of claims 1, 2 and 5-17 over Lewis in view of Lowenstein is requested.

(9) Appendix

Claims:

1. A process for the production of potassium hydroxy citric acid, which potassium hydroxy citric acid is not in the form of a lactone, comprising the steps of:

- a) providing Garcinia fruit;
 - b) extracting the Garcinia fruit with an alkyl alcohol to obtain an extract;
 - c) repeating step b) to obtain another extract;
 - d) combining the extracts of steps b) and c) to obtain a combined extract;
 - e) treating the combined extract with potassium hydroxide to obtain a treated extract;
 - f) refluxing the treated extract to obtain potassium hydroxy citrate precipitate;
 - g) isolating the precipitate;
 - h) washing the precipitate with an alkyl alcohol to obtain a washed precipitate;
- and thereafter
- i) drying the washed precipitate to obtain dried potassium hydroxy citric acid.

2. The process of claim 1 comprising:

- a) providing Garcinia fruit;
- b) extracting the Garcinia fruit with methanol at reflux temperature and collecting the extract;
- c) repeating step b) an additional two times;
- d) combining the three extracts of steps b) and c);

e) treating the combined extracts with methanolic potassium hydroxy at about pH 10 and reflux for about three hours to precipitate potassium hydroxy citrate;

f) filter the precipitate;

g) wash with methanol and dry under vacuum; and

h) mill, sift, blend, and pack the dried product under nitrogen.

5. A new technological process for commercial manufacturing of potassium hydroxy citric acid from natural source, which potassium hydroxy citric acid is not in the form of a lactone, said process comprising the steps of:

a) providing Garcinia fruit;

b) extracting the Garcinia fruit with an alkyl alcohol to obtain an extract;

c) repeating step b) an additional two times to obtain another extract;

d) combining the extracts of steps b) and c) to obtain a combined extract;

e) treating the combined extract with potassium hydroxide to obtain a treated extract;

f) refluxing the treated extract to obtain potassium hydroxy citrate precipitate;

g) isolating the precipitate;

h) washing the precipitate with an alkyl alcohol to obtain a washed precipitate; and thereafter

i) drying the washed precipitate to obtain dried potassium hydroxy citric acid.

6. The new technological process according to claim 5, further comprising milling, sifting, blending and packing the dried potassium hydroxy citric acid under nitrogen.
7. The compound made by the process of claim 5 which contains not less than 50% of hydroxycitric acid in free acid form.
8. The compound made by the process of claim 5 which contains 33 to 38% of elemental potassium.
9. The composition made by the process of claim 5 which is soluble in water.
10. The compound made by the process of claim 5 which is not hygroscopic.
11. The compound made by the process of claim 5 which has specific rotation $(-)\text{20}^{\circ}$ to $(-)\text{23}^{\circ}$ on anhydrous basis.
12. The compound made by the process of claim 5 which does not convert to lactone form.
13. The compound made by the process of claim 5 which is stable for 5 years under normal storage conditions.

14. The compound made by the process of claim 5 which is more bioavailable to inhibit cytoplasmic enzyme citrate lyase.

15. The compound made by the process of claim 5 which provides potassium to enter in chemical reaction with chromium and vanadium to enhance biological effect of hydroxycitric acid in oxidizing or burning fats - the effect that results in a weight loss.

16. The process of claim 5, wherein the Garcinia fruit is *Garcinia cambogia* or *Garcinia indica* fruit.

17. The process of claim 16, wherein the Garcinia fruit is *Garcinia cambogia*.